UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF PRINCETON, WEST VIRGINIA,
a West Virginia municipal corporation,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., McKESSON CORPORATION, PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., MALLINCKRODT PLC, MALLINCKRODT LLC., SPECGX LLC; WAL-MART STORES EAST D/B/A WAL-MART PHARMACY WAREHOUSE #45,

Defendants.

CIVIL ACTION NO. 1:18-cv-01242

COMPLAINT

DEMAND FOR JURY TRIAL

PRELIMINARY STATEMENT

1. Plaintiff, the City of Princeton, West Virginia, brings this civil action to eliminate the hazard to public health and safety, to abate the public nuisance caused by the opioid

epidemic in the City and to compensate the City for abatement measures undertaken or underway and damages sustained as a result of the opioid epidemic proximately caused by Defendants.

2. This drug crisis began with a corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly joined by other manufacturers, including Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; SpecGx LLC, (collectively the "Marketing Defendants").

3. Marketing Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. all of whom used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1]

4. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses,

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

5. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[2] Consequently, the market for prescription opioids was sharply constrained.

6. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by the other Marketing Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

7. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram

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[2] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

8. Thus, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. Further, according to the CDC, one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription.[3] That number increases to 1 in 32 for patients receiving 200 MMEs per day.[4] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[5]

9. Once the Marketing Defendants created mass market for prescription opioids, McKesson Corporation, AmerisourceBergen Drug Corporation, and Cardinal Health, Inc. (together "Wholesaler Defendants" or "Distributor Defendants") flooded it. Distributor Defendants are responsible for delivering opioids marketed and made by the Marketing Defendants to pharmacies throughout the country. Distributor Defendants have a duty under state law and federal law to report and to not ship suspicious orders of controlled substances including orders of opioids that exceed reasonable volume or frequency, into the City. Yet, Distributor Defendants have supplied opioids in quantities that they knew or should have known

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[3] Thomas R. Frieden, M.D. and Debra Houry, M.D., *Reducing the Risks of Relief –The CDC Opioid-Prescribing Guideline* at 1503, NEJM, April 21, 2016.

[4] 90 MME is approximately 230 mg of OxyContin.

[5] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

exceed any legitimate market for opioids—even the wider market for chronic pain-and ignored red flags of suspicious orders of these drugs in the City, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

10. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

11. In the last six years, drug wholesalers have showered the state of West Virginia with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians have fatally overdosed on those two painkillers. The unregulated shipments amount to 433 pain pills for every man, woman and child in the state of West Virginia.

12. As a direct and foreseeable result of Defendants' conduct, the nation and the City are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[6] In 2014, almost 2 million Americas were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

[6] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, Apr. 29, 2014, available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, Aug. 2016, available at http://turnthetiderx.org.

13. The increased volume of opioid prescribing, correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. According to the National Bureau of Economic Research, 85% of opioid-related deaths are due to increased prescribing of opioids.[7] Nationally, the number of deaths due to drug overdoses rose from 16,849 in 1999 to 63,632 in 2016.[8] The United States Center for Disease Control ("CDC") estimates that nearly two-thirds of the drug overdose deaths in 2016 were due to opioids.[9] The number of deaths associated with this crisis is expected to be even higher in 2018.

14. West Virginia had the highest drug-overdose death rate in the US in 2014, 2015, and again in 2016, according to CDC reports.[10] In 2016, the drug overdose death rate was 52.0 deaths per 100,000 people.[11] The state also has one of the highest prescription rates of opioids in the United States.[12] West Virginia ranks in the top 10 for the highest rate of prescriptions given out for high-dose opioids and extended-release opioids both of which are targets for abusers.

15. The Defendants' actions, motivated by financial gain without regard to the welfare of the City of Princeton and its residents, have caused substantial damages, including, but not limited to, increased expenses of drug abuse treatment programs, prevention and training costs (for law enforcement, hospitals and schools), costs of the drug Naloxone as well as education,

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[7] Christopher J. Ruhm, National Bureau of Economic Research Paper, *Deaths of Despair or Drug Problems?*, Jan. 2018.
[8] *Id.*
[9] https://www.cdc.gov/drugoverdose/
[10] http://www.cdc.gov/drugoverdose/data/statedeaths.html.
[11] *See* CDC Drug Overdoses Mortality by State "2016 tab", located at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm; CDC Drug Overdoses Mortality by State "2015 tab" located at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last visited on April 5, 2018).
[12] http://www.businessinsider.com/these-are-the-states-prescribing-the-most-opioid-painkillers-2016-3.

training and use, youth development community programs, medical care and hospitalizations, increased costs of law enforcement, increased costs of prosecutions and most significantly increased costs of incarcerations.

16. Defendants' conduct in promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. Plaintiff has borne these costs for the benefit of its community, as have other local governments. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

17. The burdens imposed on Plaintiff are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

18. The City of Princeton has been severely damaged by Defendants' collective actions. The Defendants have illegally and tortiously profited from the prescription drug abuse problems knowingly dumping opioids into the City of Princeton. Further, many users of prescription opioids, which at the molecular level and in their effect, closely resemble heroin, have turned to heroin after becoming addicted to, but no longer able to obtain, prescription opioids. The devastation caused by the Defendants goes beyond and cannot be adequately

conveyed by recounting the economic damage; the City of Princeton's families have lost children, parents and grandparents. This epidemic of opioid abuse caused by the Defendants has taken and destroyed the lives of many residents of the City of Princeton.

19. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

20. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers will earn over $2.7 million from the sale of opioids.

21. The City brings this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

PARTIES

I. PLAINTIFF

22. The Plaintiff, the City of Princeton, West Virginia is a public corporation which may sue and plead in its own name. W. Va. Code § 7-1-1(a) [2008]. Plaintiff is a "political subdivision" and is neither an agency nor an agent of the State of West Virginia. W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

II. DEFENDANTS

A. Marketing Defendants

23. At all relevant times, the Marketing Defendants, each of whom is defined below, have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription

opioid drugs. The Marketing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

1. Purdue Entities

24. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

25. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

26. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

27. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally including the following:

Product Name	**Chemical Name**	**Schedule**[13]
OxyContin	Oxycodone hydrochloride, extended release	Schedule II
MS Contin	Morphine sulfate, extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

[13] Since passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* ("CSA" or "Controlled Substances Act"), opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

28. Purdue made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

29. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

30. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

2. Janssen Entities

31. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

32. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

33. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

34. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

35. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

36. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally. Among the drugs Janssen manufactures or manufactured are the following:

Product Name	**Chemical Name**	**Schedule**
Duragesic	Fentanyl	Schedule II
Nucynta[14]	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

37. Janssen made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

[14] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

38. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments.

39. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

40. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

3. <u>Endo Entities</u>

41. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

42. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

43. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, "Endo") manufacture opioids sold nationally, and in Princeton. Among the drugs Endo manufactures or manufactured are the following:

Product Name	**Chemical Name**	**Schedule**
Opana ER	Oxymorphone hydrochloride, extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II
Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II
Generic	Hydrocodone	Schedule II

44. Endo made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

45. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15

billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

46. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

4. <u>Cephalon Entities</u>

47. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

48. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

49. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the following opioids in the United States, Mercer County, and Plaintiff's Community:

Product Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl buccal	Schedule II

50. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in West Virginia, many of whom were not oncologists and did not treate

cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services but in fact to deceptively promote and maximize the use of opioids.

5. Mallinckrodt Entities

51. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

52. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and

acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

53. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

54. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

55. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	**Chemical Name**	**Schedule**
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II

Product Name	**Chemical Name**	**Schedule**
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule III

56. Mallinckrodt made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

57. Collectively, Purdue, Cephalon, Janssen, Endo, and Mallinckrodt are referred to as "Marketing Defendants."[15]

58. Marketing Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.

B. <u>Distributor Defendants</u>

59. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Princeton. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual

[15] Together, Purdue, Cephalon, Janssen and Endo are also sometimes referred to as "RICO Marketing Defendants."

revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

60. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal office located in Dublin, Ohio. Cardinal is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Through its various DEA registered subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1990. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

61. Defendant McKesson Corporation ("McKesson"), is registered with the West Virginia Secretary of State as a Delaware corporation with its principal office located in San Francisco, California. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

62. Defendant Wal-Mart Stores East, L.P., is a Delaware limited partnership with its principal office located in Bentonville, Arkansas, doing business as Wal-Mart Pharmacy Warehouse #45 ("Wal-Mart").

63. AmerisourceBergen, Cardinal, McKesson and Wal-Mart are collectively referred to herein sometimes as "Distributor Defendants" or "Wholesaler Defendants."

64. Together, Purdue, Cephalon, Endo, Mallinckrodt, Cardinal, McKesson, and AmerisourceBergen are sometimes referred to as "RICO Supply Chain Defendants."

65. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.

III. AGENCY AND AUTHORITY

66. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

IV. JURISDICTION AND VENUE

67. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, raise a federal question. This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

68. This Court personal jurisdiction over each defendant as they conduct business in the State of West Virginia, where this action was originally filed, purposefully direct or directed their actions toward the State of West Virginia, some or all consented to be sued in the State of West Virginia by registering an agent for service of process, because they consensually submitted to the jurisdiction of the State West Virginia when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State of West Virginia necessary to constitutionally permit the Court to exercise jurisdiction. This Court also

has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring the members of the nationwide RICO enterprise before the court in a single trial.

69. Venue as to each Defendant is proper in the Southern District of West Virginia under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Southern District of West Virginia. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in that district.

70. JURY DEMAND

71. Plaintiff demands a jury trial pursuant to Federal Rule of Civil Procedure 38.

V. **STATEMENT OF FACTS**

72. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Marketing Defendants turned that consensus on its head by falsely denying the risk of addiction and overstating the benefits of using opioids long-term.

73. Through marketing that was as pervasive as it was deceptive, Marketing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue promoted the concept that pain was undertreated, that opioids could not be

abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted.

74. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Marketing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), [16] who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Marketing Defendants' marketing claims.

75. Marketing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

76. Marketing Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Marketing Defendants.

[16] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

77. Purdue recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.

78. Marketing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from the Marketing Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One notable KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

79. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, which also took money directly from Marketing Defendants in an organized effort to exert greater influence because of their seeming independence. According to a report issued by the U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, "many patient advocacy organizations and professional societies

focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[17] These "front groups" for the opioid industry put out unbranded patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Marketing Defendants distributed these publications to prescribers, including, upon information and belief, prescribers in the City, or posted them on their websites.

80. These third-party, unbranded materials were not reviewed or approved by the FDA. The FDA does not regulate all conduct engaged in by these Defendants. Marketing for chronic pain is not specifically approved. Medication labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia—three conditions for which opioids are not effective, but for which these Defendants marketed their drugs. Nor do the labels approve of the concept of pseudoaddiction or the technique of suggesting that abuse deterrent formulations are safer. In addition, though labels contain warnings about addiction, they do not quantify the severity of the risk. Marketing Defendants' asserted in branded and unbranded marketing that screening, abuse deterrent formulations, or urinalysis could adequately manage the risk of developing an addiction without evidence to support these claims.

81. Upon information and belief, all of the messages described below were disseminated to Princeton prescribers and patients.

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[17] U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic*, Feb. 12, 2018, https://www.hsdl.org/?abstract&did=808171 at 3 (hereinafter, "*Fueling an Epidemic*").

1. Minimizing or mischaracterizing the risk of addiction.

82. To convince prescribers and patients that opioids are safe, Marketing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

83. Marketing Defendants undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. These Defendants also minimized the difficulty of withdrawal in their marketing material and promotional programs. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

84. Marketing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in various editions from 2008-2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or

addicted to opioids. The FDA has determined that the risks of addiction and overdose are present when opioids are taken as prescribed.[18] Purdue knew that individuals who resort to injecting or snorting opioids are uncommon, and they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

85. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"), over which Purdue and other Defendants exercised control. For example, *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

86. *A Policymaker's Guide to Understanding Pain & Its Management,* also taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use, even when gradually tapering off.

87. Purdue published a "Training Guide for Healthcare Providers" in 2010 that claimed: "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." This publication also claimed that patients

[18] Letter from Janet Woodcock, M.D., Dir. of Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

88. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, which downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

89. Purdue and Endo sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book sought to reassure veterans about addiction by explaining that although they may become physically dependent on opioids, they will not become addicted:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly . . . Physical dependence is normal. This does not mean you are addicted. Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

(Emphasis in original).

90. Endo sponsored a website, *Painknowledge.com*, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

91. Endo also distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com.

92. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Until recently this guide was still available online.

93. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

94. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."

95. Among its content, the website contained a handout titled *Oxycodone Safety for Patients*, released in June 2007, which advised doctors that "[p]atients' fears of opioid addiction should be dispelled." The handout misleading stated that "[a]ddiction to oxycodone in persons without a recent history of alcohol or drug problems is rare." It also misleadingly characterized

withdrawal symptoms as occurring only if medication is suddenly stopped and suggested that gradually lowering the dose as a way to "help prevent" withdrawal symptoms, which the handout characterized mildly as merely "uncomfortable" symptoms that may include "diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings." This handout is still available to prescribers and patients today.

96. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), which targeted veterans and misleadingly portrayed addiction as resulting only from recreational use or other intentional abuse of opioids and misleadingly suggested that patients using the drugs as prescribed would not become addicted, or even experience withdrawal symptoms upon discontinuing the drugs, unless their dosage were stopped or lowered too abruptly:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goose bumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly. . . . Physical dependence is normal. This does not mean you are addicted. Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

97. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt describes C.A.R.E.S as its own advocacy program, and promised "[t]hrough the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take."

98. The C.A.R.E.S. Alliance publicly describes itself as "[c]reated with leading pain experts through a scientific process" and offering "free resources" to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid pain medications. It further described the "safe-use programs and voluntary tools" it developed as "grounded in science and research." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

99. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!*. This book is still available online in Plaintiff's Community and elsewhere. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "[I]n our experience, the issue of tolerance is overblown."

- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

100. Mallinckrodt's former parent Company, Covidien, published a patient resource, "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

101. Marketing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. According to one study, nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.[19] Addiction can result from the use of any opioid, "even at recommended dose"[20] and the risk increases with chronic (more than three months) use. The CDC has emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[21]

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[19] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study,* 26 J. Gen. Internal. Med. 1450 (2011).

[20] *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18, 2016), https://www.magmutual.com/learning/article/fda-announces-safety-laveling-changes-and-postmarket-study-requirements-opioids.

[21] Deborah Dowell, Tamara M. Haegerich, Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain*, Morbidity and Mortality Weekly Report, March 18, 2016, 65(1); 1-49 ("CDC Guideline").

2. Marketing Defendants falsely described addiction as pseudoaddiction and dangerously encouraged doctors to respond by prescribing more opioids.

102. Marketing Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called "pseudoaddiction." Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

103. Purdue, through its unbranded imprint *Partners Against Pain*,[22] promoted the concept of pseudoaddiction through at least 2013 on its website. It disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an American Pain Society ("APS") consensus statement through the website, where APS, who received funding from Defendants, defined pseudoaddiction in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused . . . Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may 'clock watch,' and may otherwise seem inappropriately 'drug seeking.' Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. . . . A patient who is physically dependent on opioids may sometimes continue to use these [medications] despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

[22] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

104. The Federation of State Medical Boards ("FSMB"), a trade organization representing state medical boards, finances opioid- and pain-specific programs through grants from Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

105. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

106. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

107. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

108. Marketing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

109. The FAQs section of *pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

110. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[23] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[24]

3. <u>Overstating the efficacy of screening tools.</u>

111. Marketing Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

[23] CDC Guideline at 13.
[24] *Id*. at 25.

112. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

113. These Defendants conveyed these safe prescribing messages in nationally distributed marketing materials. A catalogue distributed by Purdue to prescribers across the country and, on information and belief, in the City, included information on screening tools. On information and belief, none of the Defendants disclosed the lack of evidence for efficacy of these tools.

114. Marketing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by or were available online, to Princeton prescribers.

115. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

116. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, from the City, attended these conferences.

117. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

118. The CDC Guideline confirmed the falsity of Marketing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for

[opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[25]

B. MARKETING DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE.

1. Mischaracterizing the benefits of and evidence for long-term use.

119. Purdue's profits, and, upon information and belief, the profits of the other Marketing Defendants, depend on keeping patients on opioids on an ongoing basis. According to internal documents, 87% of Purdue's OxyContin business is driven by continuing prescriptions. Thus, recurring prescriptions to chronic pain patients is a key component of Purdue's business model.

120. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[26] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[27] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[28] As a result, the

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[25] CDC Guideline at 28 (emphasis added).
[26] *Id.* at 10.
[27] *Id.* at 9.
[28] Woodcock Letter, *supra*.

CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

121. Nevertheless, upon information and belief, Marketing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

122. In addition, two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Marketing Defendants. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S. Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Purdue and Teva, along with several other pharmaceutical drug companies.[29] Upon information and belief, Marketing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

[29] Letter from Ron Wyden, Ranking Member, U.S. Senate Committee on Finance, to Honorable Thomas E. Price, Secretary, U.S. Health & Human Services (May 5, 2017), https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf.

123. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[30]

124. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Marketing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

125. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

126. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high

[30] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

127. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. These Guidelines were available to Princeton prescribers.

128. Purdue specifically marketed its opioids for chronic pain conditions such as low back pain and osteoarthritis, using "vignettes," or patient exemplars, illustrating the use of opioids to treat patients with these conditions, and inviting doctors to identify patients with these conditions as appropriate candidates for its opioids. Purdue also acknowledged its strategy to encourage prescribers to switch patients from nonsteroidal anti-inflammatory drugs ("NSAIDs," over-the-counter, non-narcotic pain relievers such as ibuprophen) through articles in "reputable journals" such as AAPM's and "hearing from respected physicians."

129. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the

role of opioids in a chronic condition such as OA [osteoarthritis]."[31] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[32] This statement is not supported by the data—a substantial proportion of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

130. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

131. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

132. Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. This campaign included the use of CMEs, speaker programs, KOLs, and journal supplements to give doctors the false impression that Actiq and

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[31] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).
[32] *Id.*

Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

133. For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

134. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

135. In December 2011, Teva widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)"* to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in the City. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

136. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses.

137. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include

mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can develop when when the medications are used as prescribed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

138. Marketing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

139. Marketing Defendants' materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving" "[d]aily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, starting in at least May of 2011, Endo distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

140. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that

"[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

c. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

d. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site.

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

141. Mallinckrodt followed suit, stating on its website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[33]

142. Likewise, Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence

[33] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporate-responsibility/responsible-use

indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

143. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[34] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

144. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[35] The CDC Guideline, following a "systematic review of the best available

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[34] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?.

[35] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that opioid manufacturer Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their

evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[36] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[37]

3. **Omitting or mischaracterizing adverse effects of opioids.**

145. In materials Defendants produced, sponsored, or controlled, these Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[38]

146. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Marketing Defendants routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[39] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the

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overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[36] CDC Guideline at 2, 18.

[37] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, NEJM, Apr. 21, 2016 at 1503.

[38] Donald Teater, M.D., *Evidence for the Efficacy of Pain Medication,* National Safety Council, October 2014.

[39] *See* Martin, *supra*.

drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

147. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids).[40] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

148. APF's *Exit Wounds*, sponsored by Purdue and Endo and aimed at veterans, omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

149. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

150. Marketing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal

[40] The higher figure reflects deaths from all causes.

bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

151. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the "adverse effects" of opioids.[41]

152. Again, Marketing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

C. MARKETING DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS.

153. Marketing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail in Section D, Purdue encouraged doctors to

[41] Meredith Noble M., *Long-Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

154. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

155. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

156. *A Policymaker's Guide,* the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids. Until recently, this publication was still available online.[42]

157. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

158. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

159. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

160. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed

[42] *See* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf .

dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

161. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

162. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[43] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[44]

D. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

163. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

[43] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[44] CDC Guideline at 16.

164. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing, including, upon information and belief, to prescribers in the City, that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

165. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

166. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue doses"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least

once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

167. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[45] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

168. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage."

169. While Purdue's commitment to marketing opioids as a 12-hour drug made it more addictive, Purdue falsely promoted OxyContin as providing "steady state" relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse.

170. Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect

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[45] Harriet Ryan, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, L.A. Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, but disregarded that responsibility in its pursuit of a marketing advantage.[46]

171. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. According to a CDC clinical evidence review, higher opioid doses are related to increased risks of motor vehicle injury, opioid use disorder, and overdoses, and the increased risk increases in a dose-dependent manner.[47] With higher doses, patients experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[48]

E. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS.

172. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid

[46] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

[47] Mark J. Edlund, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain,* 30 Clin. J. Pain 557–564 (2014); Woodcock Letter, *supra*.

[48] CDC Guideline at 16.

addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in the City.

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

173. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse-deterrent properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

174. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

175. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks

these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[49]

176. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[50] and is still regularly tampered with and abused.

177. Websites and message boards used by drug abusers and others, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected.

178. *One-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in drug abuse, as many addicts simply shifted to other drugs such as heroin.

179. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the

[49] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/.

[50] Hr'g Test. of Dr. Mohan Rao at 1615:7-10, In re OxyContin, No. 1:04-md-01603-SHS (SDNY Oct. 7, 2013), ECF No. 613.

article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

180. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[51] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[52]

181. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated OxyContin product has had a meaningful impact on abuse."[53] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

182. Despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

[51] CDC Guideline at 22 (emphasis added).
[52] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, AP (Jan. 2, 2017), https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution.
[53] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

2. Endo's Deceptive Marketing of Reformulated Opana ER.

183. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

184. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse."[54] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

185. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug.

[54] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-2228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

186. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[55] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[56]

187. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[57]

188. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injection and more easily be prepared for injection[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—

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[55] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).
[56] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).
[57] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

189. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

190. Nevertheless, Endo continued to market the drug as tamper-resistant and abuse-deterrent and did not disclose evidence that Opana was easier to abuse intravenously.

191. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[58] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[59] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[60]

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[58] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).
[59] *Id*.
[60] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

192. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."

193. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New York Attorney General also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in the City.

F. PURDUE MISREPRESENTED ITS COOPERATION WITH LAW ENFORCEMENT.

194. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[61]

195. As described in Section A.3, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

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[61] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

196. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

197. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[62] Purdue's statement on "Opioids & Corporate Responsibility" likewise states that "[f]or many years, Purdue Pharma has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government agencies."[63] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[64]

198. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

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[62] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.
[63] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility/.
[64] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

G. DEFENDANTS DELIBERATELY DISREGARDED THEIR DUTIES TO REPORT AND TERMINATE SUSPICIOUS ORDERS.

1. Defendants have a duty to report suspicious orders and not to ship those orders unless due diligence disproves their suspicions.

199. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids and a lucrative opportunity for Wholesaler Defendants, who compounded this harm by failing to maintain effective controls against diversion and instead facilitating the supply of far more opioids that could have been justified to serve that market and supplying opioids they knew or should have known were being abused or diverted. Wholesaler Defendants' failure to investigate, report, and terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties, and upon information and belief, all Defendants' failure to report and cease supply suspicious prescribers or filling suspicious orders, breach their statutory and common law duties.

200. First, by flooding the City with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, these Defendants breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to the City.

201. Second, each Defendant assumed a duty, when speaking publically about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

202. Third, the Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances, 21 U.S.C. §§801–971 (2006);

21 *C.F.R.* §§1300–1321 (2009), as does West Virginia law, which is no less stringent than the CSA. *See, e.g.*, 15 CSR 2.4.

203. Defendants owe a duty under West Virginia state law, 15 CSR 2.4 and federal law, 21 U.S.C. § 823, 21 CFR 1301.74, to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from and around Princeton, West Virginia.

204. The foreseeable harm from a breach of this duty is the diversion and use of prescription opiates for nonmedical purposes.

205. Defendants repeatedly and purposefully breached their duties under federal and state law which is a direct and proximate cause of the diversion of millions of prescription opiates for nonmedical purposes in and around Princeton, West Virginia.

206. The unlawful diversion of prescription opiates is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality in Princeton, West Virginia.

207. The unlawful diversion of prescription opiates is a direct and proximate cause of the opioid epidemic currently plaguing the City of Princeton, West Virginia.

208. The opioid epidemic in City of Princeton, Virginia, remains an immediate hazard to public health and safety.

209. The opioid epidemic in City of Princeton, West Virginia, is a public nuisance and remains unabated.

210. The main objectives of the CSA are to prevent or alleviate drug abuse and to control the legitimate and illegitimate trafficking of controlled substances. In enacting the CSA Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory

system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping. *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

211. The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880. Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

212. "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

213. Distributors of Schedule II drugs—controlled substances with a "high potential for abuse," 21 U.S.C. §§ 812(b), 812(2)(A)-(C)—must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and

industrial channels," *id.* § 823(b)(1). In addition, distributors that supply controlled substances to pharmacies must "design and operate a system to disclose to the [distributor] suspicious orders of controlled substances" and, in turn, disclose those suspicious orders to the DEA. 21 C.F.R. § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206–07 (D.D.C. 2012).

214. Federal regulations issued under the CSA further mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."[65]

215. The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. 1970 U.S.C.C.A.N. 4566, 4571-72.

[65] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter "2006 Rannazzisi Letter").

216. Distributor Defendants are ". . . one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated September 27, 2006 ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

217. "Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry. U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated December 27, 2007, ("This letter is being sent to

every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).")

218. The closed system of the CSA is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted from this closed system. Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶8, *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 2012 WL 11747342 (US Dist. DC 2012).

219. Defendants have a duty to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels. *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

220. Federal law imposes a duty upon the Defendants to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels. 21 U.S.C.A. § 823(b)(1).

221. Federal law imposes a duty upon the Defendants to comply with applicable State and local law. 21 U.S.C.A. § 823(b)(2).

222. The West Virginia Legislature enacted the West Virginia Wholesale Drug Distribution Licensing Act of 1991, W. Va. Code § 60A-8-1 *et seq.* [1991], to protect the health, safety, and general welfare of residents of this state and further authorized and directed the board of pharmacy to promulgate rules to carry out its purpose.

223. West Virginia state law imposes a duty upon the Distributor Defendants to provide effective controls and procedures to guard against diversion of controlled substances. 15 CSR 2-4.2.1.

224. West Virginia state law imposes a duty upon the Defendants to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 15 CSR 2-4.4. *See also* W.Va. Code § 60A-1-101 *et seq.*

225. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All flagged orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.[66]

226. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that wholesalers and manufacturers of controlled substances alike

[66] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of West Virginia); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

227. Further, these laws and industry guidelines make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

228. Defendants have a duty to, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

229. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opiates for nonmedical purposes.

230. The foreseeable harm resulting from the diversion of prescription opiates for nonmedical purposes is abuse, addiction, morbidity and mortality in the City of Princeton and the damages caused thereby.

2. <u>Defendants understood the importance of their reporting obligations.</u>

231. As explained above, the reason for the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[67] Both because wholesale distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal

[67] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[68]

232. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences. In fact, trade organizations to which Defendants belong have acknowledged that wholesale distributors such as Defendants have been responsible for reporting suspicious orders for more than 40 years.[69] The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which a number of Defendants, including Defendants AmerisourceBergen, Cardinal, McKesson, H.D. Smith, Endo, Purdue, Mallinckrodt, and Cephalon belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[70] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are

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[68] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[69] *See* Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .") (emphasis omitted).

[70] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[71]

233. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[72]

234. The FTC, too, has recognized the unique role of wholesale distributors. Since their inception, Wholesaler Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, these Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Wholesaler Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Wholesaler Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with generic manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses

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[71] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

[72] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

within the pharmaceutical industry, as well as the assortment of additional services they offer, Wholesaler Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

235. As both a manufacturer and distributor, Mallinckrodt too, has unique insight into ordering patterns and activities of downstream customers. In a recent settlement with the DEA, Defendant Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)."[73] This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well. The practice of obtaining "chargeback" data would have enabled Mallinckrodt not only to see red flags in the orders it filled itself as a wholesaler, but also additional red flags from the added data it received from its distributor customers.

236. Further, even if law enforcement is alerted to some activity, an investigation and enforcement action would take time, during which opioids would continue to be diverted, and enforcement officials may not be able to identify or curtail diversion by all downstream participants, whom Defendants could have cut off promptly at the source.

237. Over the last several years, the DEA has provided briefings to wholesale distributors and conducted a variety of conferences regarding their duties under federal law. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how

[73] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[74] Distributors such as Cardinal, McKesson, and AmerisourceBergen attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

238. The DEA also, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included the Wholesaler Defendants) that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[75] The DEA's September 27, 2006 letter also expressly reminded them that registrants, *in addition* to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[76]

[74] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *anufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[75] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[76] *See* 2006 Rannazzisi Letter.

239. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[77] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). The letter explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders <u>when discovered</u> by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern

[77] *See* 2007 Rannazzisi Letter.

> throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect to suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

240. Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[78]

[78] *See* 2007 Rannazzisi Letter.

3. Defendants worked together to sustain their market and boost their profits.

241. As leading wholesale distributors, Distributor Defendants had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

242. Wholesaler Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

243. Upon information and belief, each of the Defendants also worked together through trade or other organizations, such as the HDA, the National Association of Chain

Drugstores ("NACDS"),[79] and Pain Care Forum ("PCF"), to safeguard the market for Marketing Defendants' opioids and the distribution of opioids.[80]

244. Upon information and belief, the HDA and the Wholesaler Defendants sought the active membership and participation of manufacturers by advocating that one of the benefits of membership included the ability to develop direct relationships between manufacturers and distributors at high executive levels. The HDA touted the benefits of membership to manufacturers, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[81]

245. After becoming members, the wholesalers and manufacturers alike were eligible to participate on councils, committees, task forces and working groups, including:

> a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."
>
> b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

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[79] The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies. Walgreen Company, CVS Health, Rite Aid Corporation and Walmart are members and/or have representatives on the Board of Directors of NACDS.

[80] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[81] Manufacturer Membership Benefits, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en..

> c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.
>
> d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.
>
> e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[82]

246. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences to manufacturers as "bring[ing] together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[83] These conferences provided HDA members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry"[84] and an opportunity for Defendants to work together.

247. Defendants also worked together through HDA and NACDS. The respective CEOs of the HDA and NACDS have spoken with one voice with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to

[82] Councils and Committees, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/about/councils-and-committees
[83] Business and Leadership Conference—Information for Manufacturers, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.
[84] *Id.*

promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

248. In addition, Defendants coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, Mallinckrodt and the Wholesalers' trade association, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[85] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, including through the enterprise described in this Complaint.

4. Despite repeated admonitions, Defendants have repeatedly violated their legal obligations.

249. A number of Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

250. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included, among others:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective

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[85] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

251. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[86] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[87] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers."

252. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain

[86] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[87] *Id.*

facilities.[88] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[89] Investigators found certain warehouses "were supplying pharmacies that sold to criminal drug rings."[90]

253. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[91]

254. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted.[92] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[93] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case"

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[88] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).
[89] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).
[90] *Id.*
[91] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.
[92] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.d6e92f349f47
[93] *Id.* (quoting a March 30, 2015 DEA memo).

reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[94] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[95]

255. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[96] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. Thats exactly what they did.[97]

256. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[98] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[99]

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[94] *Id.*
[95] *Id.*
[96] Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress
[97] *Id.*
[98] *Id.*
[99] *Id.*

257. The Wholesaler Defendants were not alone in failing to live up to their reporting obligations. As discussed above, Mallinckrodt recently paid a $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[100] In addition, Mallinckrodt admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[101]

258. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[102]

259. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied

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[100] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[101] 2017 Mallinckrodt MOA.

[102] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[103]

260. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
>
> ii. detect and report to the DEA orders of unusual size and frequency;
>
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
>
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
>
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
>
> iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing

[103] *Id.*

Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[104]

261. Mallinckrodt acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[105]

262. Mallinckrodt also agreed that, from its chargeback data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[106]

5. <u>Defendants ignored red flags of abuse and diversion.</u>

263. Each of the Distributor Defendants is registered with the DEA as distributors in the chain of distribution of Schedule II controlled substances and assumed the duties imposed under the CSA.

264. Each of the Distributor Defendants is a "registrant" as a distributor in the chain of distribution of Schedule II controlled substances and assumed the security requirement duties imposed under the regulations adopted by the West Virginia Board of Pharmacy.

265. Each of the Distributor Defendants sold prescription opiates, including hydrocodone and/or oxycodone, to retailers in Mercer County, West Virginia.

[104] 2017 Mallinckrodt MOA at 2-3.
[105] *Id.* at 3-4.
[106] 2017 Mallinckrodt MOA at 5.

266. Hydrocodone and oxycodone are Schedule II controlled substances under the CSA which have a currently accepted medical use but have a high potential for abuse, and its abuse may lead to severe psychological or physical dependence. *United States v. Bell*, 667 F.3d 431, 442 (4th Cir. 2011); 21 U.S.C. § 812(b)(2); 21 C.F.R. § 1308.12(b)(1)(xiii).

267. Hydrocodone is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid. Its street names include Hydro, Norco and Vikes. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. There are numerous brand and generic hydrocodone products marketed in the United States. All are combination products. The most frequently prescribed combination is hydrocodone and acetaminophen (for example, Vicodin®, Lorcet®, and Lortab®). Other examples of combination products include those containing aspirin (Lortab ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration. DEA Drug Fact Sheet: Hydrocodone, https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

268. Oxycodone is a semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population. Its street names include Hillbilly Heroin, Kicker, OC, Ox, Oxy, Perc, and Roxy. Oxycodone is marketed alone as OxyContin® in 10, 20, 40 and 80 mg. controlled-release tablets and other immediate-release capsules like 5 mg. OxyIR®. It is also marketed in combination products with aspirin, such as Percodan®, and with acetaminophen, such as Roxicet®. Oxycodone is abused orally or intravenously. The tablets are crushed and sniffed or dissolved in water and injected. Others heat a tablet that has been placed on a piece of foil then inhale the vapors. DEA Drug Fact Sheet: Oxycodone, https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.

269. Hydrocodone and oxycodone are opiate pain-relieving medications having an addiction-forming or addiction-sustaining liability similar to morphine. *United States v. Bell*, 667 F.3d 431, 442 (4th Cir. 2011); 21 U.S.C.A. § 802(18).

270. Prescription opiate drugs provide serious addiction or abuse problems. 1970 U.S.C.C.A.N. 4566, 4569.

271. Defendants are required under the CSA to maintain, on a current basis, a complete and accurate record of each prescription opioid received, sold, delivered, or otherwise disposed of. 21 U.S.C.A. § 827(a)(3).

272. Defendants report the sale of all prescription opiates, including those to pharmacies in Mercer County, West Virginia, to the Automation of Reports and Consolidated Orders System (ARCOS) database. *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).

273. The DEA has disclosed to the West Virginia Attorney General certain data from the ARCOS database relating to the sale of hydrocodone and oxycodone doses to retailers in West Virginia between 2007 and 2012. This information has become public knowledge as reported by the Charleston Gazette and reveals that drug wholesalers sold West Virginia pharmacies 780 million hydrocodone and oxycodone pills during this timeframe. *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette (December 17, 2016). The records also disclose the number of prescription opiates sold to each of the 55 counties in West Virginia between 2007 and 2012. The data does not disclose the distributions per pharmacy nor the monthly shipments. Nonetheless, the data reveals that the Distributor Defendants sold over 5 million doses of hydrocodone and oxycodone to pharmacies

located in and around Princeton, Mercer County, West Virginia, between 2007 and 2012. Specifically, the data reveals as follows:

MERCER COUNTY 2007-20012 (TOP WHOLESALERS)							
Defendant Wholesalers	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**Grand Total**
CARDINAL HEALTH	322,000	283,900	290,000	288,900	329,300	414,200	1,928,300
MCKESSON CORPORATION	252,700	300,100	278,400	301,600	173,800	93,000	1,399,600
AMERISOURCEBERGEN DRUG CORP	183,300	199,700	179,800	201,620	481,100	730,600	1,976,120
WAL-MART PHARMACY WHSE #45	66,900	75,100	62,600	62,400	56,700	92,400	416,100
Total	**824,900**	**858,800**	**810,800**	**854,520**	**1,040,900**	**1,330,200**	**5,720,120**

274. Defendant AmerisourceBergen more than 1.9 million doses to pharmacies in Mercer County between 2007 and 2012, directly affecting the City of Princeton.

275. Defendant Cardinal sold more than 1.9 million doses to pharmacies in Mercer County between 2007 and 2012, directly affecting the City of Princeton.

276. Defendant Wal-Mart sold more than 400 thousand doses to pharmacies in Mercer County between 2007 and 2012, directly affecting the City of Princeton.

277. Defendant McKesson sold more than 1.3 million doses to pharmacies in Mercer County between 2007 and 2012, directly affecting the City of Princeton.

278. Collectively, the Distributor Defendants sold more than 5 million doses of prescription opioids to retailers and around Princeton, Mercer County, West Virginia.

279. The sheer volume of prescription opioids distributed to pharmacies in and around Princeton is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

280. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in

quantities that they knew or should have known exceeded any legitimate market for opioids—even the wider market for chronic pain.

281. Data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

282. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

283. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described above;

d. Distributor Defendants together account for as much as 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) and information from data

> vendors that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

284. Further, prescribers in West Virginia have been convicted of crimes involving drug diversion or have been subjected to disciplinary action by the West Virginia Board of Medicine. Upon information and belief, these prescribers, and the pharmacies at which their patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Marketing and Distributor Defendants not only to an overall oversupply in Plaintiff's Community, but specific instances of diversion.

285. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years. West Virginia, in particular, has faced a spike in fatal drug overdoses, many of which are attributable to prescription opioids. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Marketing and Distributor alike thus had every reason to believe that illegal diversion was occurring in Plaintiff's Community.

286. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[107] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities,

[107] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

287. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by Defendants. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[108] The majority of pharmacies sell these records.[109]

288. This information provided a means for Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[110]

289. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

290. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail above, Defendants refused to identify suspicious orders and

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[108] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).
[109] *Id.* at 389.
[110] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

diverted drugs despite the DEA issuing final decisions against a number of Distributor Defendants.[111]

291. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> *Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?*

292. Moreover, upon information and belief, Marketing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags.

293. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[112] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to

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[111] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[112] Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2//

[the wholesaler] to make the report."[113] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

294. That Distributor Defendants failed to halt suspicious orders is further evidence by their actions in having refused to recognize any duty beyond *reporting* only some types of suspicious orders. In *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (C.A.D.C.) (April 4, 2016), the Healthcare Distribution Management Association and National Association of Chain Drug Stores submitted amicus briefs regarding the legal duty of wholesale distributors under the CSA. They argued**:**

> The "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled. Those added obligations would significantly expand the "report-only" duty of distributors under the longstanding regulatory scheme and impose impractical obligations on distributors, which occupy a fundamentally different position than the physicians who prescribe the drugs to patients or pharmacists who dispense drugs to fill those prescriptions. (emphasis in original);
>
> The "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications." (internal citations omitted) (internal quotes omitted) (emphasis in original);
>
> "Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.";

[113] *Id*.

> "The practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.";
>
> "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." (emphasis in original);
>
> "There is simply no practical way for distributors to look over the shoulder of pharmacists and doublecheck the validity of each prescription in light of an individual patient's circumstances.";
>
> "Imposing a duty on distributors- which lack the patient information and the necessary medical expertise—to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands.";
>
> "Given the unique role that distributors occupy in the healthcare system, any attempt to impose additional obligations on them to investigate and halt suspicious orders would raise serious policy and practical issues, such as the disruption of patient access to prescribed medications."

295. The positions taken by the trade groups are emblematic of the position taken by the Distributor Defendants regarding their duties under the CSA. *See* Amicus Curiae Brief of HDMA, *Cardinal Health, Inc. v. United States Dept. Justice*, (arguing the wholesale distributor industry "does not know the rules of the road" because they claim the "DEA has not adequately explained them.").

296. "Ignorance of the law excuses no one." *State v. Ross*, 70 W. Va. 549, 74 S.E. 670, 674 (1912). Further, as explained above, Defendants were well aware of their legal duties.

297. Not surprisingly, the U.S. District Court for the District of Columbia's ultimate ruling in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017), ruled consistent with *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007), and contrary to Defendants' position in this regard.

298. Rather, than abide by public safety statutes and obligations, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Dept. of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued. See Larry Bernstein and Scott Higham, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, THE WASHINGTON POST (October 22, 2016); Larry Bernstein and Scott Higham, Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis, THE WASHINGTON POST (March 6, 2017); Eric Eyre, DEA agent: 'We had no leadership' in WV amid flood of Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

299. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

300. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the

future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

301. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

302. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at

every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

303. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

304. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[114]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

305. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

[114] Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf't Admin.*, Case No. 15-1335, 2016 WL 1321983 (D.C. Cir. April 4, 2016), at *3-4, *25.

306. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..."

307. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[115]

308. As described in Section VI.F above, at the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion.

309. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

[115] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016) http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

H. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses

1. Continuing Conduct

310. Plaintiff contends that it continues to suffer harm from the unlawful actions by the Defendants.

311. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

312. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's community, that they are working to curb the opioid epidemic.

313. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

314. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

315. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived

Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

316. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiff, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

317. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's community deceived the medical community, consumers, the State, and Plaintiff's community.

318. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiff *could not identify* the potential defendants in this litigation, and further held that such information was "critical":

> *This means Plaintiff[s] still do[] not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation . . . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s'] claims, but also to the Court's understanding of the width and depth of this litigation.*

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

319. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's community. Plaintiff and Plaintiff's community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

320. The Plaintiff and Plaintiff's community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

VI. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

321. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[116] formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

322. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing

[116] The RICO Marketing Defendants referred to in this section are those named in the First Claim for Relief under 28 U.S.C. § 1964(c), including Purdue, Cephalon, Janssen, Endo, and Mallinckrodt.

Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

323. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

324. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

325. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated,

and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

326. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

327. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that

the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

328. As public scrutiny and media coverage focused on how opioids ravaged communities in West Virginia and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

329. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

330. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or

undermined the CDC Guideline, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

331. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

332. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

333. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

334. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain in West Virginia and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's health care and law enforcement systems.

335. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. **The Conduct of the Opioid Marketing Enterprise violated Civil RICO**

336. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front

Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

337. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that

representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and West Virginia. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the RICO Marketing Defendants for their financial structure and for career development and promotion opportunities.

338. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

339. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their

industry sponsors."[117] "By aligning medical culture with industry goals in this way, many of the groups described in th[e *Fueling an Epidemic*] report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[118]

340. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

341. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

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[117] *Fueling an Epidemic*, *supra* note 17, at 1.
[118] *Id*. at 2.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

342. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

343. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

344. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

345. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

346. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute

and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

347. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud West Virginia consumers, the State, and other intended victims.

348. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

349. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

350. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and Plaintiff's community;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout Plaintiff's community that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

351. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

352. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

353. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

354. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

355. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

356. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[119] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (Purdue, Cephalon, Endo, Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

357. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good.

[119] McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited Apr. 21, 2018).

CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

358. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[120] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

359. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the Rico Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

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[120] 21 C.F.R. § 1301.74(b).

360. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens . Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

361. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain

Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

362. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

363. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

364. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[121]

[121] *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce,

365. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

366. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

367. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

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http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/ (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

368. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

369. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

370. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributor Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

371. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd.,	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
	(3) Teva Pharmaceuticals USA, Inc.	Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc, (2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt plc*)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II

372. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

373. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

374. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

375. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

376. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

377. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

378. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some

instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

379. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

380. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

381. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

382. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of

willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

383. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's communities and the Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

384. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

VII. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED THE CITY OF PRINCETON AND ITS RESIDENTS.

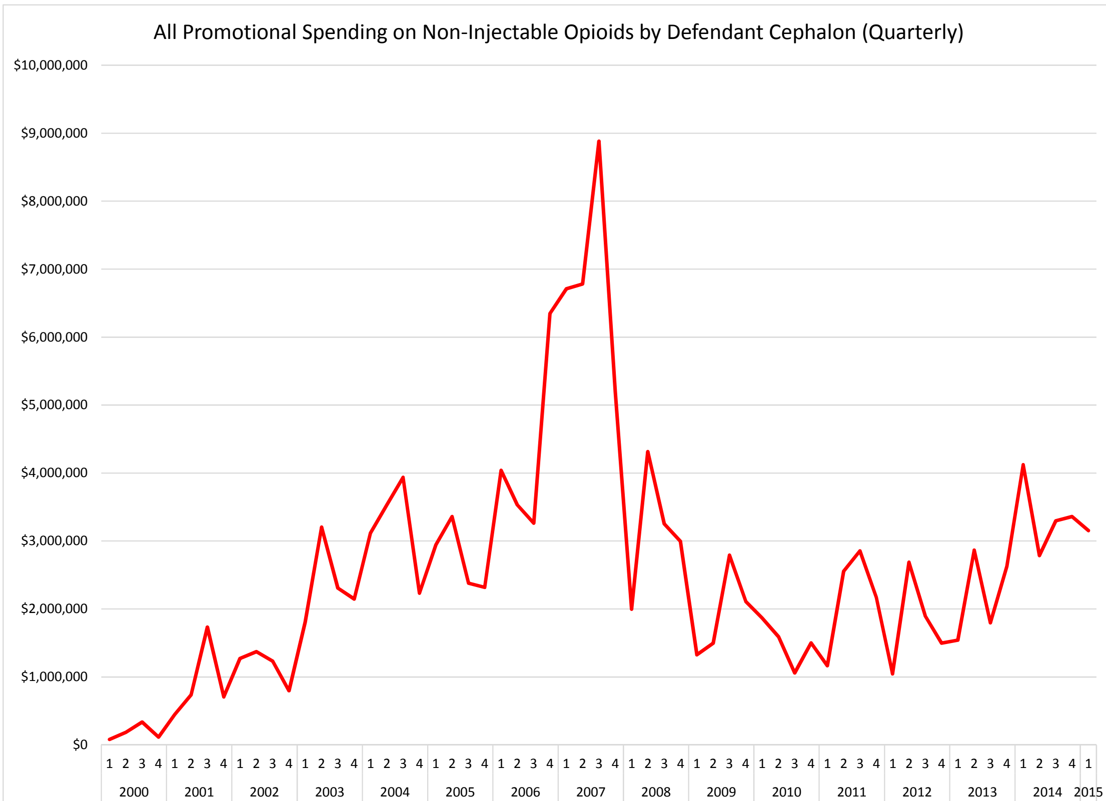
385. Marketing Defendants' misrepresentations prompted health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, these Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use.

386. Marketing Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population

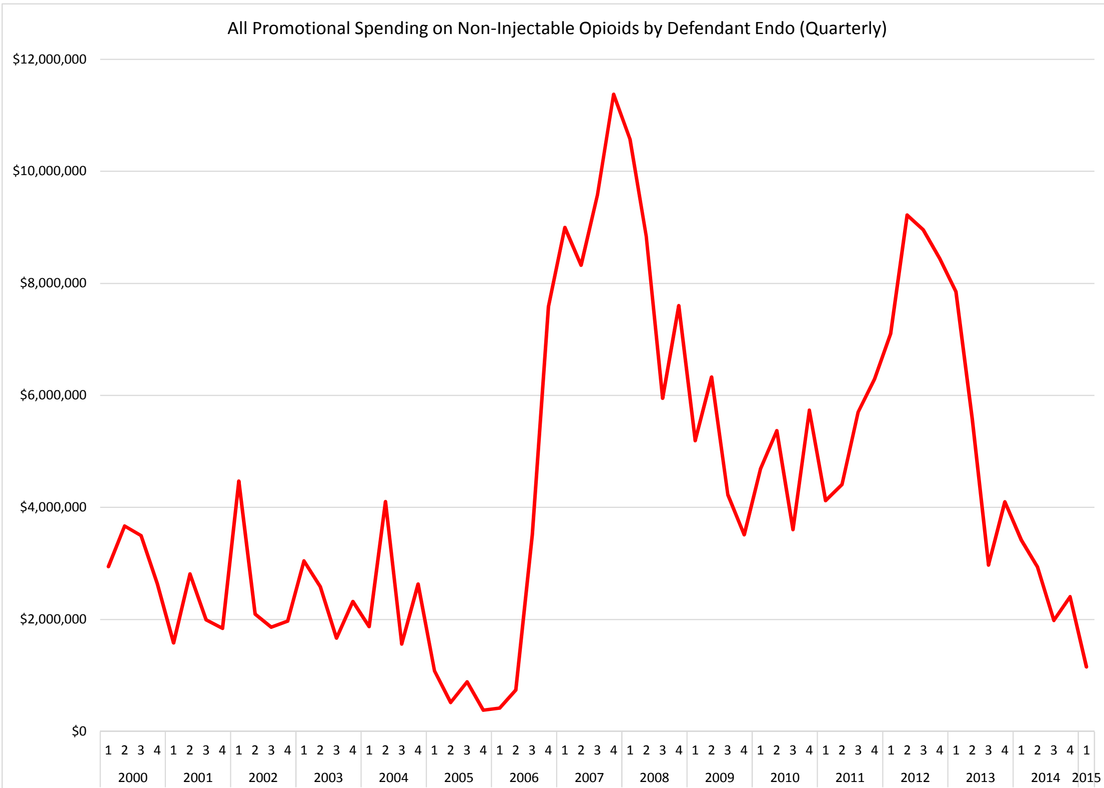
between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

387. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors.

388. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:

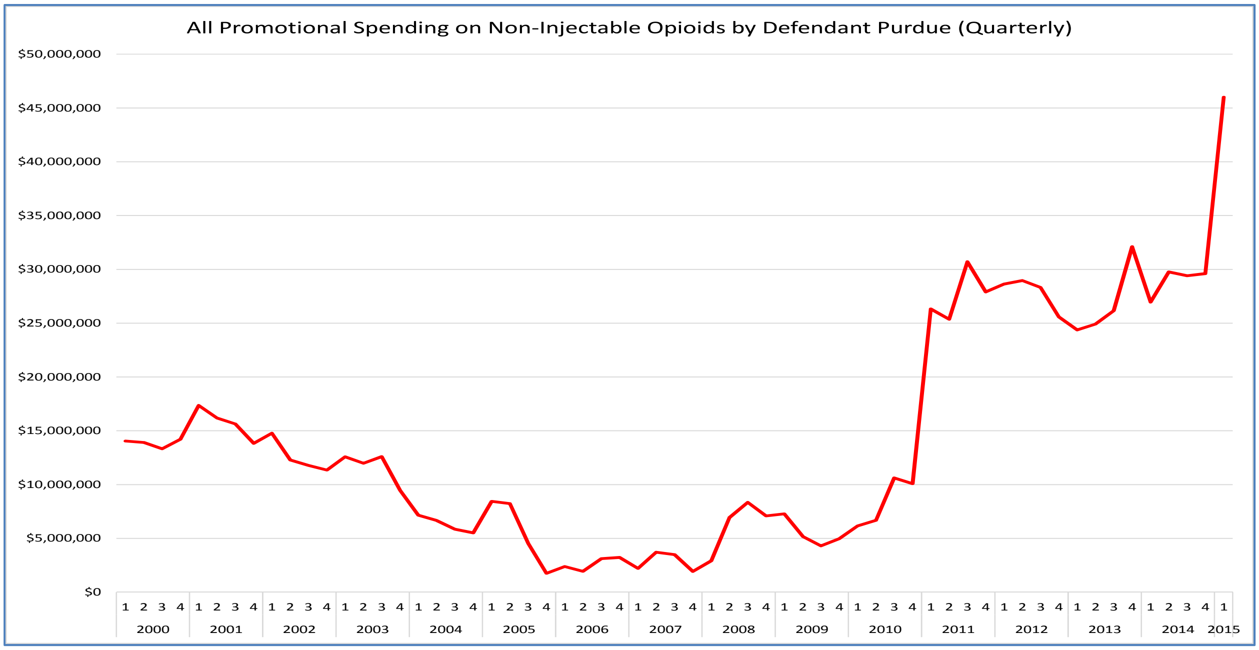


389. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



390. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:

391. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise through at least 2015, as shown



below:

392. The sharp increase in opioid use resulting from Marketing Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in West Virginia. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[122]

[122] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

393. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[123]

394. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[124]

395. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[125] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[126]

396. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[127]

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[123] *See* Murthy, *supra* note 5.
[124] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban*, *and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).
[125] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).
[126] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).
[127] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

397. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

398. Further, opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[128]

399. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications." Special Report, FDA Commissioner Robert M. Califf, M.D., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374; 1480-85 (April 14, 2016). The increased use of prescription painkillers for nonmedical reasons (without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths. Press Release, *Prescription painkiller overdoses at epidemic levels*, U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention (November 1, 2011).

400. Opioid abuse has not displaced heroin, but rather triggered resurgence in its use imposing additional burdens on the City of Princeton and local agencies that address heroin use and addiction. Princeton, West Virginia experienced 26 heroin overdoses in the span of four hours on August 17, 2016. The amount of calls that were received overwhelmed emergency responders. When the first few calls came in, three ambulances were already out dealing with overdoses. For a half-hour span, there were no ambulances available in the county to send. Eight of the victims were revived using the opioid-overdose-reversing drug naloxone and others by a

[128] Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., Opioid Abuse in Chronic Pain, NEW ENG. J. MED., 374:1253-63 (March 31, 2016).

manual resuscitator "a bag valve mask" to stimulate breathing. One victim was given three doses of naloxone.[129]

401. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. Wilson M. Compton, MPE, *Relationship between Nonmedical Prescription Opioid Use and Heroin Use*, NEW ENG. J. MED., 374:154-63 (January 14, 2016).

402. People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids.

403. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be the major drivers of the upward trend in heroin use and overdose. Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014*, Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, 64(50);1378-82 (January 1, 2016).

404. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large

[129] See http://www.cnn.com/2016/08/ 17/health/west-virginia-city-has-27-heroin-overdoses-in-4-hours/index.html

increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence.

405. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002 to 2004 to 45.2% in 2011 to 2013. Heroin produces a very similar high to prescription opioids, but is often cheaper and easier to obtain. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin (0.1g), with multiple highs, for the same price.

406. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans.

407. West Virginia has been particularly hard-hit by the opioid epidemic. The State had the highest drug-overdose death rate in the US in 2014, 2015, and 2016, according to a recent CDC report.[130] The state also has one of the highest prescription rates of opioids in the United States.[131] West Virginia ranks in the top 10 for the highest rate of prescriptions given out for high-dose opioids and extended-release opioids both of which are targets for abusers.

408. West Virginia has long been known as "coal country." Mining, timbering, and manufacturing play a huge role in West Virginia's economy.[132] They are all jobs that require heavy manual labor and leave workers prone to injury. Coal mining accounts for more than 18,000 jobs in West Virginia.[133] Although West Virginia's coal mines have lost more than 7,000 jobs since 2011, the mining industry as a whole has continued to grow in the state, thanks to

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[130] http://www.cdc.gov/drugoverdose/data/statedeaths.html.
[131] http://www.businessinsider.com/these-are-the-states-prescribing-the-most-opioid-painkillers-2016-3.
[132] http://www.seniorjobbank.org/database/West_Virginia/West_Virginia.html.
[133] http://www.nma.org/pdf/c_employment_state_region_method.pdf.

strong growth in the natural gas and oil industries. According to the US Bureau of Economic Analysis, mining accounted for 18% of the state's overall GDP in 2014.[134]

409. Mining operations proved to be flash points for opioid abuse when prescription practices liberalized, as workers tried to stave off injuries. John Temple, a professor at West Virginia University and the author of the 2015 book "American Pain", has offered:

> *In a mining camp, there aren't a lot of doctors," he said. "That doctor is going to be more likely to opt for the quick fix and give people pills to fix their pain and get them back into the mine, rather than give them rest or therapy or those things that can actually cure pain.*[135]

410. Dr. Carl "Rolly" Sullivan, who has run the addiction program at West Virginia University Hospitals since 1985, has noted the link between opioid abuse and the West Virginian economy:

> *West Virginia was ripe for the picking, We had a lot of blue-collar workers who were in farming and timbering and coal mining and things that were likely to produce injuries.*
>
> *There are a lot of dangerous occupations*" in Appalachia, he said. "*People get prescribed opioids far more frequently" for the injuries associated with them.*[136]

411. Opioid abuse was further exacerbated by a declining economy and heavy job loss in the state over the last 20 years. As of March 2016, West Virginia has the second-highest unemployment rate in the US, at 6.5%. According to a Bureau of Labor Statistics report last August, West Virginia was the only state to experience a statistically significant decrease in employment over the previous year, losing 19,100 jobs from 2014 to 2015.

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[134] https://www.afsc.org/sites/afsc.civicactions.net/files/documents/Report-state-working-west-va-2014.pdf.
[135] http://www.amazon.com/American-Pain-Unleashed-Americas-Deadliest/dp/1493007386?tag=bisafetynet-20.
[136] http://www.wvgazettemail.com/apps/pbcs.dll/article?AID=/20151017/GZ01/151019539.

412. Though the coal-mining industry has been hit hard jobs in the sector have decreased from 41,000 in 1983 to approximately 18,000 in 2016,[137] according to the Mine Safety and Health Administration, other industries were struck as bad or worse. According to The Wall Street Journal, jobs in construction and manufacturing have fallen by 23% and 16%, respectively, since the recession.[138]

413. The opioid crisis has taken an enormous toll across the nation and in the Princeton community. West Virginia has seen 3,000 drug overdose deaths in the last five years, or an average of 600 a year. In Mercer County alone, there were at least 32 overdose deaths and 360 drug overdoses, including heroin and prescription drugs in 2017.

414. The loss of life has been devastating to the community that cannot be conveyed by statistics. And, the harm extends well beyond overdoses. For example, a recent study by the Centers for Disease Control and Prevention found that hepatitis C cases in the State West Virginia have more than tripled between 2006 and 2012. The recent outbreak of hepatitis C, which can be transmitted by injecting drugs or having unprotected sex, is centered in rural areas among young, white drug users. In addition, there have been 406 drug-related arrests in Princeton this year[139]. One out of every four calls to the Princeton Fire Department involve cases of overdose. Meanwhile, residential treatment centers struggle to keep pace with the demand for addiction treatment services.

415. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton

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[137] https://www.washingtonpost.com/news/wonk/wp/2013/11/04/heres-why-central-appalachias-coal-industry-is-dying/.
[138] http://blogs.wsj.com/economics/2015/08/21/the-only-state-to-lose-jobs-since-july-last-year-west-virginia/.
[139] http://www.dailymail.co.uk/news/article-3128229/West-Virginia-rate-drug-overdose-deaths.html#ixzz4W7qD5w3j

University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

416. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (Against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants"))

417. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

418. The RICO Marketing Defendants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

419. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue Cephalon, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

420. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing

Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

421. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

422. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false messages.

423. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendants" false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

424. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

425. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

426. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

427. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

428. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

429. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

430. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

431. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to West Virginia consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

432. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including West Virginia consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own

profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

433. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

434. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

435. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive West Virginia consumers, prescribers, regulators and the Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including West Virginia consumers, prescribers, regulators and the Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

436. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

437. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

438. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

439. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent.[140] Rather, as Plaintiff alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[141] Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

[140] *Travelers Prop. Cas. Co. of Am.* v. *Actavis, Inc.*, 16 Cal. App. 5th 1026 (2017).

[141] *Id.*

440. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.[142]

441. Specifically, the RICO Marketing Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

[142] *Id.*

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

442. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

443. Plaintiff is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

444. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the

Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

a. Actual damages and treble damages, including pre-suit and post-judgment interest;

b. An order enjoining any further violations of RICO;

c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;

f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;

h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of unction; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;

m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;

n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;

o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;

p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;

q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;

s. Forfeiture as deemed appropriate by the Court; and

t. Attorney's fees and all costs and expenses of suit.

SECOND CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 *et seq*. – Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants"))

445. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

446. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

447. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

448. The RICO Supply Chain Defendants were members the Healthcare Distribution Alliance (the "HDA").[143] Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

449. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the

[143] *History*, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

450. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

451. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

452. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering

activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

453. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

454. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

455. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The RICO Supply Chain Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

456. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

457. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

458. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis—leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

459. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

460. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

461. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts

also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

462. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

463. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

464. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

465. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

466. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

467. It was foreseeable to the RICO Supply Chain Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion

of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

468. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

469. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

470. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[144] Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[145]

471. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiff in the form of substantial

[144] *Travelers Prop. Cas. Co. of Am.* v. *Actavis, Inc.*, 16 Cal. App. 5th 1026 (2017)..

[145] *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *6 (W.D. Wash. Sept. 25, 2017).

losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

472. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

473. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

474. Plaintiff's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

475. Plaintiff is most directly harmed and there are no other plaintiff is better suited to seek a remedy for the economic harms at issue here.

476. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought into the First Claim for Relief, as the Court deems just and applicable.

THIRD CLAIM FOR RELIEF

Common Law Public Nuisance
(Against All Defendants)

477. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

478. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

479. A public nuisance results from conduct that causes an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts § 821B. *See also Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009) (West Virginia's definition of nuisance is "consistent with the Restatement (Second) of Torts § 821B(1)." (quoting *Duff v. Morgantown Energy Assocs. (M.E.A.)*, 187 W.Va. 712, 421 S.E.2d 253, 257 n.6 (1992)).

480. Defendants have created and maintained a public nuisance by marketing, distributing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's Community, and Plaintiff and the residents of Plaintiff's Community have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

481. Plaintiff and Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property. Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of the Plaintiff's Community.

482. The consequences of Defendants' wrongful and illegal actions as set forth above have also resulted in an intentional invasion of the interest of Plaintiff and Plaintiff's Community in the use and enjoyment of the public and private land comprising Plaintiff's corporate boundaries.

483. The consequences of Defendants' wrongful and illegal actions as set forth above have further resulted in environmental contamination and/or damage to Plaintiff's property and property in Plaintiff's Community.

484. The public nuisance is a public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

485. Defendants have created and maintained a public nuisance through their ongoing conduct of marketing, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's Community, flooded Plaintiff's Community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff and the residents of Plaintiff's Community.

486. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and Plaintiff's Community.

487. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

488. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers have lost the value of productive and healthy employees; and

f. Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, education systems, and property maintenance and clean-up.

489. Defendants intentionally, unreasonably, and/or unlawfully deceptively marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff and Plaintiff's Community.

490. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

491. Defendants' conduct constitutes a violation of federal and West Virginia law. In the sale and distribution of opioids in West Virginia and Plaintiff's Community, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and West Virginia law, including, but not limited to W. Va. Code § 60A-8-7(c)(1)(I); W. Va.

Code § 60A-8-7(c)(3); W. Va. C.S.R. § 15-2-4. The aforesaid statutes and regulations are public safety statutes and regulations.

492. Defendants' unlawful nuisance-creating conduct includes violating federal and West Virginia statutes and regulations, including the controlled substances laws, by:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

493. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

494. Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

495. The Marketing Defendants intentionally and unreasonably engaged in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Plaintiff's Community.

496. The Marketing Defendants intentionally and unreasonably misled Plaintiff, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

497. The Marketing Defendants violated West Virginia and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

498. Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

499. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiff—exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

500. Defendants had control over their conduct in Plaintiff's Community and that conduct has had an adverse effect on rights common to the general public. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

501. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiff described herein.

502. Because of the Marketing Defendants' deceptive marketing of opioids and Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

503. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiff and Plaintiff's Community and the harm inflicted outweighs any offsetting benefit.

504. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

505. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

506. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

507. The nuisance created by Defendants' conduct has not been abated.

508. The nuisance created by Defendants' conduct is abatable.

509. Defendants' misconduct alleged in this case is ongoing and persistent.

510. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

511. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

512. Plaintiff seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

513. Plaintiff is asserting its own rights and interests and Plaintiff's claims are not based upon or derivative of the rights of others.

514. The tortious conduct of each Defendant was a substantial factor in creating the public nuisance.

515. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiff.

516. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

517. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

518. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre and post-judgment interest.

FOURTH CLAIM FOR RELIEF

Negligence
(Against All Defendants)

519. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

520. Defendants owed Plaintiff a duty to not expose Plaintiff to an unreasonable risk of harm.

521. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids.

522. Defendants had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity. *See* 21 U.S.C. §823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15- 2-4.

523. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

524. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

525. Defendants breached their duty to Plaintiff by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

526. The Marketing Defendants breached their duty to Plaintiff by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

527. Defendants engaged in conduct the foreseeable result of which was to cause harm to Plaintiff.

528. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, and sale of their prescription opioids.

529. Defendants were negligent by marketing, distributing, and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiff.

530. The method by which Defendants created this market was by marketing, distributing, and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

531. A reasonably prudent opioid manufacturer and distributor should have anticipated an injury to Plaintiff as a probable result of marketing, distributing, and selling prescription opioids in this manner.

532. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiff as described herein.

533. Defendants had control over their conduct in Plaintiff's Community. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the

Defendants controlled the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

534. Because of the Marketing Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

535. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

536. Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

537. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiff —exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

538. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities.

539. Each Defendant was required under West Virginia law to first be licensed by the West Virginia State Board of Pharmacy. W. Va. Code § 60A-8-7. To received and maintain their license, each of the Distributor Defendants has a duty to comply with federal, state, and local laws regarding the distribution of drugs. W. Va. Code § 60A-8-7(c)(1)(I); *see also* W. Va. Code § 60A-8-7(c)(3) (requiring compliance with guidelines adopted by the United States Food and Drug Administration).

540. The West Virginia State Board of Pharmacy has the authority to suspend or revoke licenses or registrations issued to Wholesale Distributors who violate Board of Pharmacy regulations. W. Va. Code § 60A-8-10(c).

541. Federal and West Virginia laws and regulations require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs. *See* 21 U.S.C. § 823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15- 2-4.

542. The federal mandates incorporated into West Virginia law require that Defendants must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(a)(1), (b)(1). These federal regulations impose a non-delegable duty upon both manufacturers and distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious

orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

543. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). Regardless, all flagged orders must be reported. *Id.*

544. Defendants violated section 60A-4-401(a) of the West Virginia Uniform Controlled Substances Act, which provides that, "Except as authorized by this act, it is unlawful for any person any person to manufacture, deliver, or possess with intent to manufacture or deliver a controlled substance."

545. Defendants' actions were not "authorized" by the West Virginia Uniform Controlled Substances Act because Defendants did not comply with the mandatory terms of the licenses issued to them by the West Virginia Board of Pharmacy or with federal requirements incorporated by reference, as further detailed in this Complaint.

546. Defendants also violated the West Virginia Board of Pharmacy Regulations which requires that "all registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." W. Va. C.S.R. §15-2-4.2.1. Additionally, the Defendants violated the regulation which requires "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the Board of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal

pattern, and orders of unusual frequency." W. Va. C.S.R. §15-2-4.4. Defendants also violated the regulation which requires "the registrant shall notify the Office of the Board of any theft or significant loss of any controlled substances upon discovery of the theft or loss as provided in subsection 8.3." W. Va. C.S.R. §15-2-4.5.

547. Plaintiff is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

548. Defendants' violations of these public safety laws are *prima facie* evidence of negligence per se. *See Waugh v. Traxler*, 186 W.Va. 355, 412 S.E.2d 756, (1991). Each Defendant had a duty under *inter alia* these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

549. West Virginia law recognizes that these violations of statutes constitute *prima facie* evidence of negligence. Syl. pt. 1, *Anderson v. Moulder*, 183 W.Va. 77, 394 S.E.2d 61 (1990); *see also* W.Va. Code § 55-7-9 ("Any person injured by the violation of any statute may recover from the offender such damages as he may sustain by reason of the violation…").

550. Marketing Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales representatives, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively withhold information about the dangers of opioids from Plaintiff, physicians, patients, and the public.

551. Defendants' conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); and West Virginia law, including, but not limited to, W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); W. Va. C.S.R. § 15- 2-4. Plaintiff was a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to Plaintiff.

552. Defendants also violated federal and West Virginia statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

553. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

554. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

555. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the Plaintiff and Plaintiff's Community.

556. Defendants' misconduct alleged in this case is ongoing and persistent.

557. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

558. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

559. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

560. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiff.

561. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

562. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

FIFTH CLAIM FOR RELIEF

Violation of West Virginia Controlled Substances Act; W.Va. Code Section § 55-7-9 (Against All Defendants)

563. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

564. The Defendants intentionally contributed to the opioid epidemic in the state of West Virginia through repeated intentional violations of various provisions of the West Virginia Uniform Controlled Substances Act and through reckless disregard to the safety and wellbeing of the citizens of the City of Princeton.

565. The Defendants intentionally failed to meet or otherwise misrepresented their compliance with the requirements of W.Va. Code § 60A-8-1 *et seq.* and otherwise intentionally violated the West Virginia Uniform Controlled Substances Act.

566. The Defendants intentionally failed to ensure their conduct conformed to industry standards, West Virginia law and other regulations.

567. The Defendants intentionally violated industry standards, West Virginia law, and other regulations by regularly distributing obscene quantities of commonly-abused, highly addictive controlled substances to clients who were serving a customer base comprised of individuals who were abusing prescription medications, many of whom were addicted and whom can reasonably be expected to become addicted or to engage in illicit drug transactions.

568. The Defendants' intentional acts and omissions have led to the dispensing of controlled substances for non-legitimate medical purposes and fueling an opioid epidemic in the City of Princeton.

569. The Defendants' intentional acts and omissions supplied millions of doses of commonly-abused, highly addictive controlled substances that supported the demands of pain

clinics that provided highly addictive prescription pain killers to individuals with no medical evidence supporting the prescription.

570. The Defendants' intentional acts and omissions fueled countless prescriptions that were primarily filled to divert the medication to illegal purposes.

571. The Defendants' intentional violations of West Virginia law make them liable for all the damages which are sustained there from W.Va. Code Section 55-7-9.

572. The Defendants' intentional acts and omissions have proximately caused and substantially contributed to damage suffered by the City of Princeton, and created conditions which contribute to the violation of West Virginia laws by others.

573. The Defendants intentional acts and omissions have proximately caused and substantially contributed to damages suffered by Plaintiff and were in violation of the customs, standards and practices within Defendants' own industries.

574. Upon information and belief, the Defendants continue to intentionally violate West Virginia laws and regulations, United States laws and regulations, and Defendants' industry customs, standards and practices which continue to proximately cause substantial damages to Plaintiff.

SIXTH CLAIM FOR RELIEF

Unjust Enrichment
(Against All Defendants)

575. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

576. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and

purchase of opioids within Plaintiff's Community, including from opioids foreseeably and deliberately diverted within and into Plaintiff's Community.

577. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

578. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

579. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

580. These expenditures have helped sustain Defendants' businesses.

581. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

582. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

583. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Marketing Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

584. Defendants have unjustly retained benefits to the detriment of Plaintiff, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

585. Defendants' misconduct alleged in this case is ongoing and persistent.

586. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

587. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

588. Plaintiff seeks an order compelling Defendants to disgorge all unjust enrichment to Plaintiff; and awarding such other, further, and different relief as this Honorable Court may deem just.

SEVENTH CLAIM FOR RELIEF

Civil Conspiracy
(Against All Defendants)

589. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

590. Defendants engaged in a civil conspiracy in their unlawful and tortious marketing of opioids and/or distribution of opioids into West Virginia and Plaintiff's Community as set forth herein.

591. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into West Virginia and Plaintiff's Community.

592. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

593. The Marketing Defendants further unlawfully marketed opioids in the West Virginia and Plaintiff's Community in furtherance of that conspiracy.

594. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiff's Counts for violations of RICO.

595. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

596. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

597. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

598. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

599. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

600. Defendants' misconduct alleged in this case is ongoing and persistent.

601. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

602. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

603. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

EIGHTH CLAIM FOR RELIEF

Punitive Damages
(Against All Defendants)

604. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

605. A Plaintiff is entitled to punitive damages under West Virginia Law if the Plaintiff establishes that Defendants' actions were the result of the conduct that was carried out by the Defendants with actual malice toward the Plaintiff and/or a conscious, reckless and outrageous indifference to the health, safety and welfare of the Plaintiff and others. W. Va. Code § 55-7-29.

606. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants

knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

607. By engaging in the wrongful conduct described herein above, Defendants engaged in willful misconduct and exhibited an entire want of care that would raise the level of actual malice and/or a conscious, reckless and outrageous indifference to indifference to the health, safety and welfare of the Plaintiff and others.

PRAYER FOR RELIEF

608. Plaintiff respectfully requests that this Court enter an order of judgment granting all relief requested in this Second Amended Complaint, and/or allowed at law or in equity, including:

a. abatement of the nuisance;

b. actual damages;

c. treble or multiple damages and civil penalties as allowed by statute;

d. punitive damages;

e. exemplary damages;

f. disgorgement of unjust enrichment;

g. equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;

h. forfeiture disgorgement, restitution and/or divestiture of proceeds and assets;

i. attorneys' fees;

j. costs and expenses of suit;

k. pre- and post-judgment interest; and

l. such other and further relief as this Court deems appropriate.

Respectfully submitted,

THE CITY OF PRINCETON,
By Counsel:

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